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10/589,871	08/18/2006	Rene Roscher	27579U	3799

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NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER	
CHONG, YONG SOO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/589,871
Filing Date: August 18, 2006
Appellant(s): ROSCHER ET AL.

Joshua B. Goldberg
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/26/2011 appealing from the Office action mailed 1/5/2010.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The 103(a) obviousness rejection of claims 1, 4, 8-11, 19 as being obvious over Noe et al. (US Patent 6,613,795 B2) in view of Wurst et al. (US Patent Application 2007/0025923 A1) was made in the Final Rejection filed on 1/5/2010 as necessitated by the new claim amendments.

Appellant made new grounds of arguments in the Appeal Brief filed on 1/26/2011, which were persuasive to withdraw the 103(a) obviousness rejection

of claims 1, 4, 8-11, 19 as being obvious over Noe et al. (US Patent 6,613,795 B2) in view of Wurst et al. (US Patent Application 2007/0025923 A1).

Since these new arguments were never presented before filing of the Appeal Brief, the Examiner did not have an opportunity to respond before the Appeal Brief. Therefore, the following new rejection, Noe et al. (US Patent 6,613,795 B2) in view of Postma et al. ("Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening" *European Respiratory Journal*, 2001; 17: 1083-1088), will now apply. Please note that the new rejection below is substantially similar to the previous rejection of record.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Noe et al. (US Patent 6,613,795 B2)

Wurst et al. (US Patent Application 2007/0025923 A1)

Postma et al. ("Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening" *European Respiratory Journal*, 2001; 17: 1083-1088)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1, 4, 8-11, 19 are rejected under 35 U.S.C. 103(a) as being obvious over Noe et al. (US Patent 6,613,795 B2) in view of Postma et al. ("Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening" *European Respiratory Journal*, 2001; 17: 1083-1088).

The instant claims are directed to a dry powder inhalation product consisting of (3R,2'R)-3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%), ciclesonide, and lactose monohydrate.

Noe et al. teach a method of treating obstructive respiratory diseases, such as asthma and bronchitis, by administering a dry powder formulation consisting of (3R,2'R)-3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%) and lactose monohydrate (examples and claims).

Examiner notes that the limitation drawn to once or twice daily treatment of a clinical condition for which a corticosteroid and/or an anticholinergic agent as well as the limitation drawn to suitable administrations are given little patentable weight since the claims are drawn to a composition. Furthermore, the instant claims do not recite any component in the composition that would distinguish it from a composition that does not recite these limitations.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or

structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

However, Noe et al. fail to disclose ciclesonide.

Postma et al. teaches the treatment of asthma by the inhaled corticosteroid, ciclesonide, which provided significantly improved asthma control (title and abstract).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine ciclesonide, as taught by Postma et al. with the composition consisting of (3R,2'R)-3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%) and lactose monohydrate, as taught by Noe et al.

A person of ordinary skill in the art would have been motivated to combine ciclesonide with (3R,2'R)-3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%) and lactose monohydrate because: (1) Postma et al. teaches that the treatment of asthma by administering ciclesonide, which significantly improves asthma control; and (2) Noe et al. teaches a method of treating respiratory disease, such as asthma and bronchitis, by administering (3R,2'R)-3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%) and lactose monohydrate in a dry powder formulation. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating asthma or bronchitis by administering a dry powder formulation consisting of (3R,2'R)-

3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidium bromide (with a minimum ee of 90%), ciclesonide, and lactose monohydrate.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

(10) Response to Argument

Appellant argues that the Wurst et al. reference is not valid prior art because the instant application and the Wurst et al. application were subject to an obligation of assignment to the same entity - "Altana Pharma AG" of Konstanz, Germany. Therefore, the Wurst et al. reference clearly falls within the 35 USC 103(c)(1) exception and does not qualify as prior art against the present application and cannot be relied on to attempt to establish a prima facie case of obviousness.

This is persuasive and accordingly the prima facie case of obviousness of Noe et al. (US Patent 6,613,795 B2) in view of Wurst et al. (US Patent Application 2007/0025923 A1) has been withdrawn. The following new rejection of Noe et al. (US Patent 6,613,795 B2) in view of Postma et al. ("Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening" *European Respiratory Journal*, 2001; 17: 1083-1088) will now apply.

Examiner notes that the two obviousness rejections are substantially similar in that the secondary references (Wurst and Postma et al.) provides the same teaching that ciclesonide is useful for treating asthma.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or

other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Remy Yucel/

Director, Technology Center 1600

Respectfully submitted,

/Yong S. Chong/

Yong S. Chong
Primary Examiner
Art Unit 1627

ysc
3/4/2011

Conferees:

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

/Shengjun Wang/

Primary Examiner, Art Unit 1627